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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,201	02/28/2002	David J. Glass	REG 910A	8028
7590	04/05/2004		EXAMINER WEBER, JON P	
Laura J. Fischer Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/086,201	GLASS, DAVID J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jon P Weber, Ph.D.	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Status of the Claims***

Claims 1-44 have been presented for examination.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 19-23, drawn to a method of inhibiting muscle atrophy/inducing hypertrophy with inhibitor of SHIP2 pathway, classified in class 514, subclass unknown inasmuch as the inhibitor is unidentified.
- II. Claims 10-14, drawn to a first method of screening for agents that inhibiting muscle atrophy/inducing hypertrophy, classified in class 435, subclass 7.21.
- III. Claims 15-18 and 22-23, drawn to a method of inhibiting muscle atrophy/inducing hypertrophy with an activator of the P13/Akt pathway, classified in class 514, subclass unknown inasmuch as the inhibitor is unidentified.
- IV. Claim 24, drawn to a cell construct, classified in class 435, subclass 325.
- V. Claim 25, drawn to an antagonist of SHIP2, unidentified and unclassifiable.
- VI. Claims 26-34, drawn to a second method of screening for agents that inhibiting muscle atrophy/inducing hypertrophy, classified in class 435, subclass 7.2.
- VII. Claim 35, drawn to a method of assaying for muscle atrophy, classified in class 435, subclass 196.
- VIII. Claim 36, drawn to a method inhibiting muscle atrophy/inducing hypertrophy with a modulator of SHIP2, classified in class 514, subclass unknown inasmuch as the modulator is unidentified.

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- IX. Claims 37-39, drawn to a method of treating diseases with a modulator of SHIP2 or the Akt pathway, classified in class 514, subclass unknown inasmuch as the modulator is unidentified.
- X. Claims 40-44, drawn to a third method of screening for agents that inhibiting muscle atrophy/inducing hypertrophy, classified in class 435, subclass 21.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions methods I and III are drawn to using inhibitors of different pathways, whereas IX is drawn to modulators of one or the other of these pathways. Modulators may enhance as well as inhibit the pathway. On its face acting on different pathways implies different compounds acting in different ways on different targets.

Inventions II, VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each of these screening assays assesses for different properties using different components and obtaining different results.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case other screening assays are shown.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Group VIII does not require a disease state and is limited to one of the two pathways of Group IX.

Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Group V is an antagonist that may or may not have been obtained by means of one of the screening assays, while Group VIII is not a screening assay but an activity assay. Neither is necessarily directly related to any of the other groups.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

### *Species*

Claims 25 and 26 are each generic to a plurality of disclosed patentably distinct species comprising:

- a) effected pathway for Group V, claim 25

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b) detection method for Group VI, claims 26-34.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species if one of these two Groups is elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

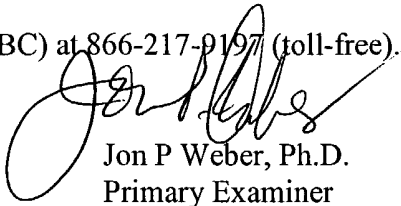
This is a restriction election only.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
2 April 2004